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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,116	07/31/2003	Houdin Dehnad	50623.249	7743

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EXAMINER	
ANDERSON, JAMES D	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 09/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/631,116	DEHNAD, HOUDIN	
	Examiner	Art Unit	
	James D. Anderson	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-48 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-48 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-26, drawn to a method of manufacturing a drug eluting implantable medical device, classified in class 424, subclass 423.

Please note additional election of species requirement outlined below if this group is elected.

II. Claims 27-42, drawn to a method of manufacturing a drug eluting implantable medical device, classified in class 424, subclass 423.

Please note additional election of species requirement outlined below if this group is elected.

III. Claim 43, drawn to a method of manufacturing a drug eluting stent, classified in class 424, subclass 423.

Please note additional election of species requirement outlined below if this group is elected.

IV. Claims 44-46, drawn to a system for manufacturing a drug eluting implantable medical device, classified in class 427, subclass 457+.

V. Claims 47-48, drawn to a system for directing a beam of charged particles to a drug eluting implantable medical device, classified in class 427, subclass 457+.

The inventions are distinct, each from the other because of the following reasons:

Inventions IV/V and I/II/III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using

the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the methods of using the products of Groups IV and V do not require the specific limitations of the claimed products. For example, the implantable medical devices of Groups I, II and III require that the devices have compositions applied to them which include a polymer and an active agent. The products of Groups IV and V do not have this limitation (*i.e.* the products, as claimed, only require a medical device, but said medical device is not required by the claim limitations of Groups IV and V to have a composition applied it). Further, the products of Group IV and V require a "beam" of charged particles or some means to focus the charged particles (*e.g.* a mask). The methods of Groups I, II and III do not require this limitation. All that is required in the manufacture of a drug eluting medical device in Groups I, II and III is a source of "charged particles".

Inventions I and II are directed to related methods of manufacturing a drug eluting implantable medical device. The related inventions are distinct if the inventions as claimed do not overlap in scope, *i.e.*, are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the related methods have a different design and mode of operation. The method of Group I has different method steps than the method of Group II. For example, the claims of Group I do not require the method step of applying a composition to an implantable medical device as required in the method of Group II. Further the composition applied in the method steps of Group II includes a solvent whereas the composition applied in the method of Group I

does not require a solvent. Further still, the method of Group I requires a means to control the duration in which the coating of the device is exposed to charged particles (*e.g.* claim 1 recites "for a duration"). The method of Group II does not have this limitation. Finally, the method of Group II requires a modification of the release rate of the active agent from the coating of the medical device whereas the method of Group I does not have this limitation. As such, the claims of Groups I and II have materially different designs and modes of operation.

Inventions I/II and III are directed to related methods of manufacturing a drug eluting implantable medical device. The related inventions are distinct if the inventions as claimed do not overlap in scope, *i.e.*, are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the related methods have a different design and mode of operation. For example, the method of Group III requires a biodegradable polymer whereas the methods of Groups I and II only require a polymer. The polymer recited in claims dependent from claim 1 (Group I) and claim 27 (Group II) would not be considered by one of ordinary skill in the art to be biodegradable polymers.

Inventions IV and V are directed to related systems for manufacturing drug eluting implantable medical devices. The related inventions are distinct if the inventions as claimed do not overlap in scope, *i.e.*, are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the related methods have a different design and mode of operation. For example,

the system of Group V requires "an accelerator capable of ionizing gaseous molecules". The system of Group IV does not require an accelerator, nor does it require that the charged particles come from gaseous molecules.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. Further, because Groups I/II/III and IV/V are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Election of Species Requirement

Claims 1, 27 and 43 are generic to the following disclosed patentably distinct species: the multitude of compounds encompassed by the term "active agent". The species are independent or distinct because "active agent" can be "any substance capable of exerting a therapeutic or prophylactic effect" (specification, page 7). Thus, "active agent" includes therapeutics with different structures, classification and modes of action (*e.g.* anticancer agents, antifungal agents, etc.). For example, 5-fluorouracil and rapamycin (recited in claim 17) are both included in the limitation "active agent." However, these two therapeutics clearly have different structures, classification and modes of action. To search the entire scope of "active agents" would present an undue search burden on the examiner. Thus, if applicant elects Group I, Group II or Group III, applicant is further required under 35 U.S.C. § 121 to elect a single disclosed species (*i.e.* a single active agent), even though this requirement is traversed. Applicant is advised that a reply

to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Notice of Possible Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

James D. Anderson
Patent Examiner
AU 1614

August 24, 2006

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER